Proposal for Collaborative Participation in the INCONTECT Project - Cohort Study

Below, we want to introduce and provide more detailed information about the cohort study phase of an important research initiative within the larger INCONTECT project. This project, funded by the Swedish Research Council (Vetenskapsrådet), focuses on addressing Incontinence-Associated Dermatitis (IAD), a condition that significantly impacts the lives of individuals dealing with incontinence.

Cohort study overview:

Background:

People living with incontinence are at risk of developing Incontinence-Associated Dermatitis (IAD), a form of irritant contact dermatitis resulting from prolonged skin contact with urine and/or faeces. The INCONTECT project aims to develop a predictive IAD model, clinically test it, and assess its applicability in clinical practice.

Objective:

The primary objective of this prospective cohort study is to assess identified risk factors for their association with Incontinence-Associated Dermatitis (IAD).

Methodology:

Patient Inclusion: During the cohort study phase, we aim to include a total of 1037 patients with urinary, faecal, or double incontinence who are free of IAD at inclusion, distributed across participating hospitals.

Patient Distribution over time: Patient recruitment for the cohort study does not need to happen all at once. We understand the challenges hospitals face in terms of staff availability and patient load. The study is designed to accommodate a longer recruitment period. Considering the 15-month study duration, this would entail an average of about 70 patients to be included each month. When distributed across the participating hospitals, it translates to roughly 11 patients per month per hospital, distributed across various participating wards.

Data Collection:

- *Patient enrolment*: Patients will be enrolled at admission and monitored throughout their incontinence episode or until discharge from the hospital.
- *Skin assessments*: Routine care, such as patient washing, will serve as the backdrop for skin assessments. These assessments will focus on specific areas, including the perianal area, labial folds, vulva, scrotum, groin, buttocks, gluteal cleft, and inner and posterior thighs.
- *GLOBIAD-M Instrument*: The validated Ghent Global Incontinence-Associated Dermatitis Monitoring Tool (GLOBIAD-M) will be utilized for data collection. This tool ensures a standardized and reliable approach to evaluating and documenting the severity of Incontinence-Associated Dermatitis.
- *Retrospective Data Collection*: Nurses will also retrospectively collect data from medical records regarding certain risk factors, such as whether the patient suffers from diabetes mellitus, age, sex, and other relevant information.
- *Training Program*: A comprehensive training program ensures that your staff is well-equipped for both prospective and retrospective data collection. This program emphasizes differential diagnosis skills between pressure ulcers and IAD. All data collectors, including nurses working on the ward and involved in daily patient care, will receive extensive training from our research team to ensure high-quality data collection.
- *Data Validation*: Digital images of IAD lesions will be taken and reviewed remotely by a blinded researcher, ensuring an additional layer of validation.

Data Management: A secure web application (REDCap) will be used to build and manage the study database.

Benefits for the participating hospital:

- **Clinical Impact:** Direct involvement in advancing patient care and outcomes in the field of incontinence management.
- **Research Collaboration:** Collaboration with our research team will provide access to cutting-edge research and expertise.

Details and Expectations for Hospital Staff:

We understand the challenges hospitals face, particularly regarding nursing staff shortages. We want to highlight that data collection will seamlessly integrate into routine observational care, such as during patient washing. Our comprehensive training program aims to minimize the impact on staff time while ensuring the highest data quality. The commitment is designed to be practical and aligned with daily patient care practices.

Reimbursement and Incentives:

While direct financial reimbursement is currently unavailable, participating hospitals will be acknowledged in any subsequent publications arising from the study. Furthermore, an exclusive invitation to a dedicated study day is extended, where we will present and discuss the results. This collaboration not only positions your hospital as contributors to the largest study in this field but also holds the potential to pave the way for a globally applicable risk prediction tool.

We kindly request your support and collaboration in this important research endeavour. Your participation in the cohort study phase of the INCONTECT project will make a substantial contribution to improving patient care and outcomes in the field of incontinence care.

Yours sincerely,

On behalf of the INCONTECT Research team

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